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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/830,071	04/23/2004	Kishore M. Gadde	1579-904	7687

23117 7590 04/13/2005

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EXAMINER	
JONES, DWAYNE C	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/830,071	GADDE ET AL.	
	Examiner	Art Unit	
	Dwayne C. Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/31/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-43 are pending.

2. Claims 1-43 are rejected.

Information Disclosure Statement

3. The information disclosure statements filed on January 31, 2005 have been reviewed and considered, see enclosed copies of PTO FORM 1449.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating obesity with the anticonvulsants of zonisamide and topiramate and the compound of bupropion which enhances the activity of norepinephrine and/or dopamine, does not reasonably provide enablement for other anticonvulsants as well as other compounds that are known functionally which enhance the activity of norepinephrine and/or dopamine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re

Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The instant invention is directed to treating obesity as well as reducing the risk of hypertension, diabetes or dyslipidaemia. The method comprises administering anticonvulsants as well as other compounds that are known functionally which enhance the activity of norepinephrine and/or dopamine.

(2) The state of the prior art

The compounds of the inventions are anticonvulsants, namely topiramate and zonisamide, that are known to treat obesity, see Shank of U.S. Patent No. 6,071,537 and Ayala, R., respectively. In addition, the compounds of Gadde, K. et al. teach of the administration of bupropion.

(3) The relative skill of those in the art

The relative skill of those in the art of pharmaceuticals is high.

(4) The predictability or unpredictability of the art

The unpredictability of the pharmaceutical art is very high. In fact, the courts have made a distinction between mechanical elements functioning the same in different circumstances, yielding predictable results, but chemical and biological compounds often react unpredictably under different circumstances. Nationwide Chem. Corp. v. Wright, 458 F. Supp. 828, 839, 192 USPQ 95, 105(M.D. Fla. 1976); Aff'd 584 F.2d 714, 200 USPQ 257 (5th Cir. 1978); In re Fischer, 427 F.2d 833, 839, 166 USPQ 10, 24 (CCPA 1970). Thus, the physiological activity of a chemical or biological compound is considered to be an unpredictable art. For example, in Ex Parte Sudilovsky, the Court held that Appellant's invention directed to a method for preventing or treating a disease known as tardive dyskinesia using an angiotensin converting enzyme inhibitor involved unpredictable art because it concerned the pharmaceutical activity of the compound. 21 USPQ2d 1702, 1704-5 (BDAI 1991); In re Fisher, 427 F.2d 1557, 1562, 29 USPQ, 22 (holding that the physiological activity of compositions of adrenocorticotropic hormones was unpredictable art; In re Wright, 999 F.2d 1557, 1562, 29 USPQ d, 1570, 1513-14 (Fed. Cir. 1993) (holding that the physiological activity of RNA viruses was unpredictable art); Ex Parte Hitzeman, 9 USPQ2d 1821, 1823 (BDAI 1987); Ex Parte Singh, 17 USPQ2d 1714, 1715, 1716 (BPAI 1990). Likewise, the physiological or pharmaceutical activity of all anticonvulsants and compounds that are known functionally which enhance the activity of norepinephrine and/or dopamine prior to filing of the instant invention was an unpredictable art.

(5) The breadth of the claims

The instant claims are very broad. For instance, claim 1 is directed to the plethora of compounds that are embraced by the generic description of anticonvulsant as well as the functional recitation of being known as a compound that enhances the activity of norepinephrine and/or dopamine. The breadth of claims was a factor in Amgen v. Chugai Pharm. Co., 927 F.2d 1200, 18 USPQ2d (Fed. Cir.),cert. Denied, 502 U.S. 856 (1991). In the Amgen case, the patent claims were directed to DNA sequences that encoded amino acid sequences. Because a very small change in the amino acid sequence of a protein can result in a very large change in the structure-function activity of a protein and because the laws of protein folding are in such a primitive state, predicting protein structure (and hence, activity) while knowing only the sequence of the protein is akin to predicting the weather for a date in the future.

(6) The amount of direction or guidance presented

The amount of guidance or direction needed to enable the invention is inversely related to the degree of predictability in the art. In re Fisher, 839, 166 USPQ 24. Thus, although a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more teaching or guidance is required. In re Fischer, 427 F.2d 839, 166 USPQ 24; Ex Parte Hitzeman, 9 USPQ 2d 1823. For example, the Federal Circuit determined that, given the unpredictability of the physiological activity of RNA viruses, a specification requires

more than a general description and a single embodiment to provide an enabling disclosure for a method of protecting an organism against RNA viruses. In re Wright, 999 F.2d 1562-63, 27 USPQ2d 1575. In the instant case, given the unpredictability of the physiological or pharmaceutical activity of a anticonvulsants as well as other compounds that are known functionally which enhance the activity of norepinephrine and/or dopamine to be effective in treating directed to treating obesity as well as reducing the risk of hypertension, diabetes or dyslipidaemia is insufficient for enablement. The specification provides no guidance, in the way of enablement for anticonvulsants as well as other compounds that are known functionally which enhance the activity of norepinephrine and/or dopamine other than the anticonvulsants of zonisamide and topiramate and the compound of bupropion which enhances the activity of norepinephrine and/or dopamine. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Accordingly, this is because it is not obvious from the disclosure of one species, what other species will work. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article "Broader than the

Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds that fall within the scope of a claim will possess the alleged activity. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

(7) The presence or absence of working examples

As stated above, the specification discloses anticonvulsants as well as other compounds that are known functionally which enhance the activity of norepinephrine and/or dopamine that have the ability directed to treat obesity as well as reduce the risk of hypertension, diabetes or dyslipidaemia. However, the instant specification only has enablement for the anticonvulsants of zonisamide and topiramate and the compound of bupropion, which enhances the activity of norepinephrine and/or dopamine, see Example 3 of the instant specification.

(8) The quantity of experimentation necessary

The quantity of experimentation needed to be performed by one skilled in the art is yet another factor involved in determining whether "undue experimentation" is required to make and use the instant invention. "'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.'" In re Wands, 858 F.2d 737,

8 USPQ2d 1404 (citing In re Angstadt, 537 F.2d 489, 502-04, 190 USPQ 214, 218 (CCPA 1976)). For these reasons, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine all of the anticonvulsants as well as other compounds that are known functionally which enhance the activity of norepinephrine and/or dopamine that would be enabled in this specification.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 4-9, 11-24, and 35-41 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Coffin et al. of U.S. Patent Application No. US 2001/0025038 A1. Coffin et al. teach of methods of reducing food cravings in mammals with the combined administration of antidepressant drugs, in particular bupropion, and anticonvulsant drugs, namely zonisamide, (see page 5 paragraphs 72, 76 and 78). In addition, Coffin et al. teach that these compounds may co-administered simultaneously or sequentially as well as being available in oral dosage forms, such as capsules and tablets, (see paragraph 84). Because the prior art reference of Coffin et al. teach of methods of

reducing food cravings in mammals with the combined administration of antidepressant drugs, in particular bupropion, and anticonvulsant drugs, namely zonisamide, the prior art reference of Coffin et al. inherently teaches of the single administration of zonisamide for the very same method of reducing food cravings in mammals.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-9 and 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayala, R. or Shank of U.S. Patent No. 6,071,537 both in view of Gadde, K. et al. Ayala, R. teach of the administration of zonisamide is effective in decreasing weight loss in patients, (see abstract). Shank teaches of treating obesity with the administration of compounds of formula I, including topiramate, (see column 4 and claims 1-4). The prior art reference of Gadde, K. et al. teach of the administration of bupropion for the treatment of obesity, (see abstract). "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). For these reasons, the skilled artisan would have been motivated to combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity.

12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ayala, R. or Shank of U.S. Patent No. 6,071,537 both in view of Gadde, K. et al. Ayala, R. teach of the administration of zonisamide is effective in decreasing weight loss in patients, (see abstract). Shank teaches of treating obesity with the administration of compounds of formula I, including topiramate, (see column 4 and claims 1-4). The prior art reference of Gadde, K. et al. teach of the administration of bupropion for the treatment of obesity, (see abstract). "It is prima facie obvious to combine two

compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). For these reasons, the skilled artisan would have been motivated to combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity. Moreover, it is well established in the pharmaceutical art that a method of reducing the risk of developing diabetes, as well as treating diabetes, can be achieved by treating obesity. Accordingly, it would logically follow to reduce the risk of an individual from developing diabetes can be achieved by treating obesity as clearly taught by the prior art references of Ayala, R. or Shank of U.S. Patent No. 6,071,537 both in view of Gadde, K. et al.

13. Claims 18-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayala, R. in view of Shank of U.S. Patent No. 6,071,537. Ayala, R. teach of the administration of zonisamide is effective in decreasing weight loss in patients, (see abstract). Shank teaches of treating obesity with the administration of compounds of formula I, including topiramate, (see column 4 and claims 1-4). The prior art reference of Gadde, K. et al. teach of the administration of bupropion for the treatment of obesity, (see abstract). "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re*

Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). For these reasons, the skilled artisan would have been motivated to combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity. Moreover, the skilled artisan would have additionally been motivated to treat related ailments where the eating disorders are manifested, such as with bulimia nervosa or anorexia nervosa, due to the fact that eating disorders, for instance bulimia nervosa or anorexia nervosa, obviously may be treated with pharmaceutical agents that control or suppress the appetite of an individual in need thereof, which would assist the individual by inter alia by controlling weight gain with these known compounds, such as zonisamide and topiramate.

Obviousness-type Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-10, 13-19 of copending Application No. 10/440,404. Although the conflicting claims are not identical,

they are not patentably distinct from each other because both the instant invention and copending Application No. 10/440,404 teach of treating obesity and hypertension (and diabetes or dyslipidaemia) with the administration of zonisamide or topiramate along with bupropion. For these reasons, the skilled artisan would have been motivated to combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity. Moreover, the skilled artisan would have additionally been motivated to treat related ailments where the eating disorders are manifested, such as with bulimia nervosa or anorexia nervosa, due to the fact that eating disorders, for instance bulimia nervosa or anorexia nervosa, obviously may be treated with pharmaceutical agents that control or suppress the appetite of an individual in need thereof, which would assist the individual by inter alia by controlling weight gain with these known compounds, such as zonisamide and topiramate.

16. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 1-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-34 of copending Application No. 11/058,981. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and copending Application No. 11/058,981 teach of treating obesity and hypertension (and diabetes or dyslipidaemia) with the administration of zonisamide or topiramate along with bupropion. For these reasons, the skilled artisan would have been motivated to

combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity.

18. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-33 of copending Application No. 11/059,027. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and copending Application No. 11/059,027 teach of treating obesity and hypertension (and diabetes or dyslipidaemia) with the administration of zonisamide or topiramate along with bupropion as well as its pharmacological metabolites. For these reasons, the skilled artisan would have been motivated to combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity. Moreover, it is established that metabolites or pharmacological agents are inherent with the administration of the pharmacological agent.

20. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. Claims 1-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 11/034,316. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and copending Application No. 11/034,316 teach of treating weight gain with the

administration of zonisamide or topiramate along with bupropion as well as its pharmacological metabolites. For these reasons, the skilled artisan would have been motivated to combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity. Moreover, it is established that metabolites or pharmacological agents are inherent with the administration of the pharmacological agent.

22. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see http://pair-direct.uspto.gov. As an alternate source, all U.S. patents and patent application

publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

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DWAYNE JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
April 9, 2005